

## Message Text

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14-11

ORIGIN HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-05 COME-00 EB-07 /031 R

66607

DRAFTED BY: DHEW/FDA:JRWEINROTH, MD

APPROVED BY: OES/SCI/BMP: MBEAUBIEN

DHEW/OIH:MACODDING

EUR/NE:CLFLOYD (INFO)

EUR/WE:WHMARSH (INFO)

----- 114571

R 302135Z APR 75

FM SECSTATE WASHDC

TO AMEMBASSY PARIS

AMEMBASSY LONDON

UNCLAS STATE 100751

E.O. 11652: N/A

TAGS: ETRD, EIND, TBIO, FR, UK

SUBJECT: FDA ADVISORY - INADEQUATELY LABELED AND DEFECTIVE MEDICAL  
DEVICE

1. FDA ADVISES THAT THE TRIPLE ISOLATED PRECISION PHYSIOLOGICAL  
PRESSURE TRANSDUCER, MODEL NO. 4-327-1 MANUFACTURED BY BELL  
AND HOWELL, ELECTRONICS AND INSTRUMENTS GROUP, INSTRUMENTS  
DIVISION, 360 SIERRA MADRE VILLA, PASADENA, CALIF. 91109 IS  
CONSIDERED TO BE INADEQUATELY LABELED AND DEFECTIVE FOR THE FOLLOWING  
REASON; THE PRODUCT CASING IS MADE OF PLASTIC AND THE INSTRUCTIONS  
STATE THAT THE DEVICE CAN BE STEAM AUTOCLAVED. HOWEVER, WHEN  
THE DEVICE IS STEAM AUTOCLAVED,THE PLASTIC PARTS DEFORM, THEREBY  
RENDERING THE PRODUCT NO LONGER USABLE. THE FIRM IS RECALLING  
THE DEVICE TO THE USER (HOSPITAL) LEVEL.

2. POSTS ARE REQUESTED TO DETERMINE IF FOREIGN CONSIGNEES ARE  
FAMILIAR WITH DETAILS OF RECALL.

3. FOREIGN CONSIGNEES AS FOLLOWS:

BELL AND HOWELL, S.A., ZONE SILIL, CIDEX L138, 94533 RUNGIS,  
UNCLASSIFIED

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FRANCE

BELL AND HOWELL, LTD. ALPERTON HOUSE, WEMBLY, MIDDLESEX,  
ENGLAND KISSINGER

UNCLASSIFIED

<< END OF DOCUMENT >>

## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 18 AUG 1999  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** n/a  
**Control Number:** n/a  
**Copy:** SINGLE  
**Draft Date:** 30 APR 1975  
**Decaption Date:** 01 JAN 1960  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Authority:** n/a  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01 JAN 1960  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
**Document Number:** 1975STATE100751  
**Document Source:** ADS  
**Document Unique ID:** 00  
**Drafter:** DHEW/FDA:JRWEINROTH, MD  
**Enclosure:** n/a  
**Executive Order:** N/A  
**Errors:** n/a  
**Film Number:** n/a  
**From:** STATE  
**Handling Restrictions:** n/a  
**Image Path:**  
**ISecure:** 1  
**Legacy Key:** link1975/newtext/t197504101/abbrznsx.tel  
**Line Count:** 57  
**Locator:** TEXT ON-LINE  
**Office:** n/a  
**Original Classification:** UNCLASSIFIED  
**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
**Original Previous Handling Restrictions:** n/a  
**Page Count:** 2  
**Previous Channel Indicators:**  
**Previous Classification:** n/a  
**Previous Handling Restrictions:** n/a  
**Reference:** n/a  
**Review Action:** RELEASED, APPROVED  
**Review Authority:** ShawDG  
**Review Comment:** n/a  
**Review Content Flags:**  
**Review Date:** 10 JUL 2003  
**Review Event:**  
**Review Exemptions:** n/a  
**Review History:** RELEASED <10 JUL 2003 by leeperne>; APPROVED <11 FEB 2004 by ShawDG>  
**Review Markings:**

Margaret P. Grafeld  
Declassified/Released  
US Department of State  
EO Systematic Review  
05 JUL 2006

**Review Media Identifier:**  
**Review Referrals:** n/a  
**Review Release Date:** n/a  
**Review Release Event:** n/a  
**Review Transfer Date:**  
**Review Withdrawn Fields:** n/a  
**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** FDA ADVISORY - INADEQUATELY LABELED AND DEFECTIVE MEDICAL DEVICE  
**TAGS:** ETRD, EIND, TBIO, FR, UK  
**To:** PARIS  
LONDON  
**Type:** TE  
**Markings:** Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 05 JUL 2006